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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/596,362 06/17/2000 Gregory Steiner 1986

27668 7590 11/18/2003

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HONOLULU, HI 96813

EXAMINER

EVANS, CHARESSE L

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 11/18/2003

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/596,362

Applicant(s)

STEINER, GREGORY

Examiner

Charesse L. Evans

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 10-16 is/are pending in the application.
- 4a) Of the above claim(s) 7-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 13-16 is/are rejected.
- 7) ☒ Claim(s) 10-12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Action Summary

Acknowledgement is made of the receipt of applicant's request for extension of time and amendment and response, filed July 29, 2003.

Applicant's arguments with respect to claims 1-6 and 10-16 have been considered but are moot in view of the new ground(s) of rejection.

Claims 7-9 were previously cancelled. Claims 1-6 and 10-16 are active in this action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "and/or" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Umbdenstock (US 5,332,579). Umbdenstock discloses a nutritional supplement formulated to assist the individual recovering from addictions, such as alcohol, smoking and food addictions, resist the cravings that accompany the withdrawal symptoms (Abstract; column 1, lines 25-29; column 8, lines 4-10; column 9, lines 1, 8-14, 20-23; and column 10, lines 17-20). The nutritional supplement is comprised of kava kava (column 10, line 18).

Regarding claim 13, examiner reads the claim as a composition claim comprising at least one alpha-pyrone compound. Accordingly, all that is required to anticipate the claim is the presence of the alpha-pyrone compound within the composition. Umbdenstock teaches a composition comprised of kava kava, which is an alpha-pyrone compound. In a composition, patentable weight is not given to the reason for including a component, as long as all of the necessary components are present.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6 and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Umbdenstock (US 5,332,579) in view of Cody (US 6,045,825). In view of the 102(b) discussion above, Umbdenstock is relied upon for its disclosure that the nutritional supplement is provided in oral form or for oral administration (column 11, claim 1).

The reference does not expressly teach the specifically claimed oral form to be a pill or gum, however, Cody supplies this deficiency by disclosing that the herb *Piper methysticum* can be adapted for administration in soft or hard gelatin capsule form or pill form (column 5, lines 22-28; and column 6, line 40). While the combination of references does not expressly teach the liquid administration of the component, one of ordinary skill in the art would be motivated to formulate this supplement into various oral dosage forms, with the expectation of addressing the various intake preferences of this patient population. By addressing the various intake preferences of the affected population, adaptability and compliance with a prescribed treatment

regimen are enhanced. Similarly, it is disclosed that the use of herbs in conjunction with transdermal patches is known in the art (column 2, lines 17-18).

Regarding claims 13-16, examiner reads the claims as composition claims comprising at least one alpha-pyrone compound. Accordingly, all that is required to render the claims obvious is the presence of the alpha-pyrone compound within the composition. Umbdenstock teaches a composition comprised of kava kava, which is an alpha-pyrone compound. In a composition, patentable weight is not given to the reason for including a component, as long as all of the necessary components are present. Furthermore, when a component is included in a composition, all of its properties and advantages are inherent to the composition.

Allowable Subject Matter

Claims 10-12 are objected to as being dependent upon a rejected base claim, but may be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charesse L. Evans whose telephone number is

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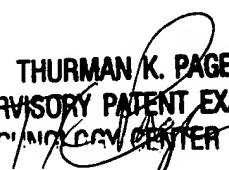
703-308-6400. The examiner can normally be reached on Monday -Thursday 7:00a - 4:30p; Alternating Fridays 7:00a - 3:30p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Charesse L. Evans
Examiner
Art Unit: 1615

November 13, 2003


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600